02833.4001LO

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Louise Humphrey
BIRGER SÖRENSEN	)	
	:	Group Art Unit: 1648
Appln. No.: 10/659,324	)	
	:	Confirmation No. 3291
Filed: September 11, 2003	)	
	:	
For: METHOD OF PRODUCING AN HIV-1 IMMUNE RESPONSE	)	
	:	October 5, 2006

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR RECONSIDERATION AND CONTINGENT PETITION
FOR WITHDRAWAL OF RESTRICTION REQUIREMENT

Sir:

This is in response to the Office Action mailed April 11, 2006, in which the Examiner made final the requirement for restriction made on December 13, 2005. For the reasons set forth below, Applicant requests that the Examiner reconsider and withdraw the requirement for restriction and examine each of Claims 16-33, 35, 37-45, 47 and 49-66 on the merits.

FACTS

1. On June 3, 2005 an Official Action was mailed requiring Applicant to elect one of SEQ ID NOS. 1, 4, 9 and 15 for examination.

2. On July 21, 2005, Applicant responded to the June 3, 2005 Official Action by electing, with traverse, the claims drawn to SEQ ID NO. 15.

3. On September 19, 2005, an Official Communication was mailed indicating that Applicant's response filed July 21, 2005 was being treated as incomplete because the response did not identify an ultimate species of generic SEQ ID NO. 15 for examination.

4. On October 19, 2005, Applicant elected, with traverse, ultimate species SEQ ID NO. 18 for examination.

5. On December 13, 2005, the Examiner mailed an additional restriction requirement, requiring Applicant to elect either the claims drawn to methods of stimulating the immune system or the claims drawn to peptides.

6. On March 13, 2006, Applicant filed a response electing, with traverse, the claims drawn to peptides.

7. On April 11, 2006, the Examiner mailed an Office Action making final the restriction requirement.

ARGUMENT

Applicant has argued repeatedly that the requirement for the election of one ultimate species of SEQ ID NO 15 for examination is contrary to the spirit of MPEP § 803.04. That section states that "normally ten sequences constitutes a reasonable number

for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction." Currently, each of the independent claims (Claims 16, 33, 45 and 53) requires the use of, or claims per se, "at least one peptide selected from the group consisting of SEQ ID NO: 16, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19 and SEQ ID NO: 20." As Applicant has previously argued, none of the factors listed in § 803.04 as necessitating a reduction in the number of sequences that may be reasonably examined (such as a recitation of three dimensional folding) are present in SEQ ID NOS: 16-20 of the present application. Further, only five SEQ ID NOS (SEQ ID NOS: 16-20) are recited in the quoted Markush group, and that these SEQ ID NOS are all related, in that they are all ultimate species of SEQ ID NO: 15. As such, Applicant previously argued that, according to the policy of the U.S. Patent and Trademark Office, for the filing fee he has paid, he is entitled, at a minimum, to the examination in this application of independent Claims 16, 33, 45 and 53 and all claims dependent therefrom. Applicant has argued that that would not constitute an unreasonable burden on the Examiner and it would further the U.S. Patent and Trademark Office's policy of aiding the biotechnology industry in protecting its intellectual property. *See id.*

In the Office Action mailed April 11, 2006, the Examiner acknowledged Applicant's arguments, but did not find them persuasive. The Examiner took the position that MPEP § 803.04 is directed to nucleic acid sequences and not amino acid sequences and that each of the amino acid sequences recited in the claims of the subject application will have their own tertiary structure. Additionally, the Examiner indicated that Applicant

has not "specifically disclosed what substantial structural feature is common to the sequences that is essential to a common disclosed utility." April 11, 2006 Official Action, p. 4. Accordingly, the Examiner deemed the restriction requirement proper and made it final.

Applicant acknowledges that the Examiner's reading of MPEP § 803.04 is technically accurate in that it discusses nucleic acid sequences and not amino acid sequences. Applicant, however, submits that the Examiner's position is contrary to the position of the U.S. Patent and Trademark Office as stated in MPEP § 803.04 and is contrary to the spirit of MPEP § 803.04. As noted above, the U.S. Patent and Trademark Office states in MPEP § 803.04 that the purpose of that section is to aid the biotechnology industry in protecting its intellectual property. *See,* MPEP § 803.04. Although MPEP § 803.04 explicitly discusses nucleic acid sequences, Applicant submits that the stated policy of the U.S. Patent and Trademark Office applies equally to nucleic acid sequences and amino acid sequences and that the spirit of § 803.04 encompasses, at a minimum, nucleic acid and amino acid sequences.

Applicant also disagrees with the Examiner's rationale for deeming the restriction requirement proper in part because each of SEQ ID NOS 16-20 has a distinct tertiary structure. Applicant notes that all amino acid and nucleic acid sequences have tertiary structures. If the Examiner's rationale and interpretation of what constitutes a burden on the Examiner is proper, MPEP § 803.04 is in essentially meaningless in that a restriction requirement limiting examination to a single sequence would always be proper.

Further, Applicant notes that MPEP § 803.04 does not indicate that normally ten sequences having a substantial structural feature common to the sequences that is essential to a common disclosed utility will be examined. Instead, the section is much broader and simply states that "normally ten sequences constitute a reasonable number for examination purposes." MPEP § 803.04. Applicant again submits that examination of each of SEQ ID NOS 16-20 fits squarely within the spirit, if not the letter, of MPEP § 803.04. Additionally, Applicant notes that if only one SEQ ID NO is to be examined at one time, Applicant will be required to file five additional patent applications to obtain coverage equal to that of, for example, Claim 33. That is, in order to obtain a patent for a claim directed to a pharmaceutical composition comprising at least one peptide selected from the group consisting of SEQ ID NO 16, SEQ ID NO 17, SEQ ID NO 18, SEQ ID NO 19 and SEQ ID NO 20, Applicant will have to file one application directed SEQ ID NO 16, one application directed to SEQ ID NO 17, one application directed to SEQ ID NO 19, one application directed to SEQ ID NO 20 and one application directed to the combination of SEQ ID NOS, in addition to the present application. Such a requirement hardly aids the biotechnology industry in protecting its intellectual property.

CONCLUSION

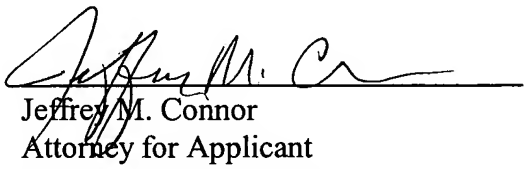
In view of the foregoing, Applicant respectfully requests that the Examiner reconsider and withdrawal the restriction requirement and examine independent Claims 16, 33, 45 and 53, and all claims dependent therefrom, on the merits.

CONTINGENT PETITION FOR WITHDRAWAL OF PURPORTED RESTRICTION REQUIREMENT

If the Examiner denies the request for reconsideration, or reconsiders, but deems the finality of the restriction requirement to be proper, Applicant requests that this paper be treated as a petition from the requirement for restriction under 37 CFR 1.144. Any fees necessitated thereby may be charged to Deposit Account No. 06-1205.

Applicant's undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 530-1010. All correspondence should continue to be directed to our below-listed address.

Respectfully submitted,



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